REMARKS

Claims 1-8, 10-23, 28-35, and 37-40, as amended, are pending in this application for the Examiner's review and consideration. Applicants appreciate the Examiner's recognition of patentable subject matter in claims 3-8, 11-13, 30-35, and 38-40. Claims 9, 24-27, and 36 were canceled without prejudice in response to a restriction requirement. Applicants reserves the right to file one or more divisional and/or continuation applications directed to the subject matter of the canceled claims or any other unclaimed subject matter.

The specification was amended to correct several occurrences of a typographical error. Specifically, the specification was amended to replace the phrase "when $R^{12'}$ is not hydroxy, it is optionally linked to X^{12} through a linker moiety L" with the phrase --when $R^{12'}$ is not hydroxy, it is optionally linked to $\underline{R^{12}}$ through a linker moiety L-- at pages 8,11, 12, 13, 14-15, 16 and 32 and to replace the phrase "$R^{12'}$ is (C_1-C_{16}) phenalkyl, or alkoxy or anhydride or hydroxy, with the proviso that when $R^{12'}$ is not hydroxy, it is optionally linked to X^{12} through an ether oxygen and wherein $R^{12'}$ is optionally terminally substituted with a therapeutic agent" with the phrase ----$R^{12'}$ is (C_1-C_{16}) phenalkyl, or alkoxy or anhydride or hydroxy, with the proviso that when $R^{12'}$ is not hydroxy, it is optionally linked to R^{12} through an ether oxygen and wherein $R^{12'}$ is optionally terminally substituted with a therapeutic agent-- at pages 9 and 17. That this is a typographical error is plainly evident from the structure of the compound of Formula III. In the compound of Formula III $R^{12'}$ is not bonded to X^{12} but is bonded to R^{12}. Accordingly, the specification was amended to be consistent with the structure of the compound of Formula III.

Similarly, claims 1, 14, 20, and 28 were amended to replace the phrase "when $R^{12'}$ is not hydroxy, it is optionally linked to X^{12} through a linker moiety L" with the phrase -- when $R^{12'}$ is not hydroxy, it is optionally linked to $\underline{R^{12}}$ through a linker moiety L--, so that the language of the claims are consistent with the structure of the compound of Formula III. As discussed above, the recitation "when $R^{12'}$ is not hydroxy, it is optionally linked to X^{12} through a linker moiety L" appears to be a typographical error and that $R^{12'}$ is

optionally linked to R^{12}, not X^{12}, through a linker moiety L is plainly evident from the structure of the compound of Formula III. Claim 1 was also amended to include the features of claim 2 and claim 2 was canceled. Claim 1 was also amended to recite that $R^{12'}$ can be an ester. Support for $R^{12'}$ being an ester comes from originally filed claim 4. Claims 3 and 4 were amended to depend from claim 1 rather than canceled claim 2. Claim 28 was amended to include the features of claim 29 and claim 29 was canceled. Claims 30 and 31 were amended to depend from claim 28 rather than canceled claim 29.

Applicants note that although the Examiner states in the Office Action at page 3 that "an action on the merits of claims 1-8, 10-23, 28-35, and 37-40 is set forth," the Examiner has not allowed, rejected, or withdrawn claims 14-23. Applicants respectfully request clarification of the status of claims 14-23.

No new matter has been added by these claim amendments so that their entry at this time is warranted.

THE REJECTION UNDER 35 U.S.C. § 102

Claims 1, 2, 10, 28, 29, and 37 were rejected as being anticipated by Surles, *American Oil Chemists Society*, 28(1), pp. 55-57 (1993) ("Surles"); Meyer, *J. Med. Chem.*, 34, 1377-1383 (1991) ("Meyer"); or Hong *et al., J. Med. Chem.*, 33, pp 1380-86, (1990) ("Hong") for the reasons set forth on page 3 of the Office Action. Applicants respectfully traverse.

Surles discloses the synthesis of four phospholipids whose structures are depicted in the reference at page 56, scheme 2, compounds 11 (a-d).

Meyer discloses a series of complex lipids whose structures are depicted in the reference at page 1379, Figures 1-4.

Hong discloses thioether lipids whose structures are depicted in the reference at page 1380, Scheme 1, compounds 9a-e.

As the Examiner is aware, to establish anticipation under 35 U.S.C. § 102(b), a single prior art reference must disclose each and every limitation of a claim either

expressly or inherently. *See Celeritas Techs. Ltd. v. Rockwell Iny'l Corp.*, 150 F.3d 1354, 1360 (Fed. Cir. 1998); *Standard Havens Prods., Inc. v. Gencor. Indus., Inc.*, 953 F.2d 1360, 1369 (Fed. Cir. 1991); *Jamesbury Corp. v. Litton Indus., Inc.* 756 F.2d (Fed. Cir. 1985); A*merican Hospital Supply v. Travenol Labs.*, 745 F.2d 1 (Fed. Cir. 1984) (holding that prior art is anticipatory only if every element of the claimed invention is disclosed in a single item of prior art). There must be no difference between the claimed invention and the reference disclosure as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research Fdn. v. Genentech*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986); *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444 (Fed. Cir. 1984) (holding that anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference). In addition, to anticipate, the reference must enable one of skill in the art to make and use the claimed invention. *In re Donahue*, 766 F.2d 531, 533 (Fed. Cir. 1985).

Independent claims 1 and 28: Neither Surles, Meyers, or Hong anticipate independent claim 1 or 28, as amended. As discussed above, Applicants have amended claim 1 to include the features of canceled claim 2 and amended claim 28 to include the features of canceled claim 29. Although the Examiner rejected claims 2 and 29 as being anticipated by Surles, Meyers, or Hong, Applicants respectfully traverse the rejection. Neither Surles, Meyers, or Hong disclose each and every feature of claims 1 and 28, as amended and, accordingly, cannot disclose each and every feature of claims 1 or 28, as amended.

Surles does not anticipate independent claim 1, as amended, or independent claim 28, as amended, since each of the compounds disclosed in Surles require that the 2-position of the phospholipid backbone is substituted with -OR, wherein R is $-CH_3$, or $-CH_2CH_3$. In contrast, the compounds claimed in independent claim 1, as amended, and the compounds included in the pharmaceutical compositions claimed in independent 28, as amended, requires that when 2-position of the phospholipid backbone is substituted with an -OR group, that R is at least 8 carbons in length. Accordingly, Surles does not disclose each and every element of independent claim 1 or 28, as amended.

Similarly, Meyers does not anticipate independent claim 1, as amended or independent claim 28, as amended. The only compounds disclosed in Meyer that are phospholipids are those disclosed in Figure 1. Each of the compounds disclosed in Meyers require that the 2-position of the phospholipid backbone is substituted with -NHC(O)R, -SR, -NHC(O)NH-R, $-SO_2R$, or -OR, wherein R is $-CH_3$, or $-CH_2CH_3$. In contrast, the compounds claimed in claim 1, as amended, and the compounds included in the pharmaceutical compositions claimed in independent 28, as amended, requires that when the 2-position of the phospholipid backbone is substituted with an -NHC(O)R, -SR, or -OR group, that R is at least 8 carbons in length. Accordingly, Meyers does not disclose each and every element of independent claim 1 or 28, as amended.

Similarly, Hong does not anticipate independent claim 1, as amended, or independent claim 28, as amended. Each of the compounds disclosed in Hong require that the 3-position of the phospholipid is substituted with a diphosphate group that is conjugated to a β-D-arabinofuranosylcytosine or cytosine residue. In contrast, the compounds claimed in claim 1, as amended, and the compounds included in the pharmaceutical compositions claimed in independent 28, as amended, require that the phosphate group(s) are bonded to a group of formula $R^3N(R^6)(R^7)R^8$. Accordingly, Hong does not disclose each and every element of independent claim 1, as amended, or independent claim 28, as amended.

Since anticipation requires that each and every element of a claim must be taught by a single prior art reference, neither Surles, Meyer, or Hong anticipate independent claim 1, as amended, or independent claim 28, as amended.

Independent claims 10 and 37: Neither Surles, Meyers, or Hong anticipate independent claim 10 or independent claim 37 since neither Surles, Meyers, or Hong disclose each and every feature of independent claim 10 or independent claim 37.

For example, Surles does not disclose any compounds wherein the 1-position of the phospholipid backbone is substituted with a -S-. In contrast, the compounds claimed in independent claim 10 and the compounds included in the pharmaceutical compositions claimed in independent claim 37 each require that 1-position of the phospholipid

backbone is substituted with a -S-, *i.e.*, X^{11} is -S-. Furthermore, as discussed above, Surles requires that the compounds disclosed therein have the 2-position of the phospholipid backbone substituted with -OR, wherein R is $-CH_3$, or $-CH_2CH_3$. In contrast, the compounds claimed in independent claim 10 and the pharmaceutical compositions claimed in independent claim 37 do not provide for the 2-position of the phospholipid backbone to be substituted with -OR, wherein R is $-CH_3$, or $-CH_2CH_3$. Rather, the compounds claimed in independent claim 10 and the compounds included in the pharmaceutical compositions claimed in independent claim 37 each require that the 2-position of the phospholipid backbone is substituted with $-X^{12}-R^{12}-R^{12'}$, wherein X^{12} is -O- and R^{12} is (C_1-C_{16}) alkyl, branched alkyl, alkenyl, or alkynyl that is then further substituted with a (C_1-C_{16}) phenalkyl or alkoxy or anhydride or hydroxy, with the proviso that when $R^{12'}$ is not hydroxy, it is linked to R^{12} through an ether oxygen and wherein R^{12} is terminally substituted with a therapeutic agent." Accordingly, Surles does not disclose each and every element of independent claim 10 or independent claim 37.

Meyers also does not anticipate independent claim 10 or independent claim 37. Meyers discloses only two compounds wherein the 1-position of the phospholipid backbone is substituted with a -S-. Each of these compounds, however, also require that the 2-position of the phospholipid backbone is substituted with -OR, wherein R is $-CH_3$, or $-CH_2CH_3$. In contrast, as discussed above, the compounds claimed in independent claim 10 and the compounds included in the pharmaceutical compositions claimed in independent claim 37 do not include compounds wherein the 2-position of the phospholipid backbone to be substituted with -OR, wherein R is $-CH_3$, or $-CH_2CH_3$. Rather, the compounds claimed in claim 10 and the compounds included in the pharmaceutical compositions claimed in independent claim 37 require that the 2-position of the phospholipid backbone is substituted with $-X^{12}-R^{12}-R^{12'}$, wherein X^{12} is -O- and R^{12} is (C_1-C_{16}) alkyl, branched alkyl, alkenyl, or alkynyl that is then further substituted with a (C_1-C_{16}) phenalkyl or alkoxy or anhydride or hydroxy, with the proviso that when $R^{12'}$ is not hydroxy, it is linked to R^{12} through an ether oxygen and wherein R^{12} is terminally substituted with a therapeutic agent." Accordingly, Meyers does not disclose each and every element of independent claim 10 or independent claim 37.

Hong also does not anticipate independent claim 10 or independent claim 37. As discussed above, each of the compounds disclosed in Hong require that the 3-position of the phospholipid backbone is substituted with a diphosphate group that is conjugated to a β-D-arabinofuranosylcytosine or cytosine residue. In contrast, the compounds claimed in claim 10 and the compounds included in the pharmaceutical compositions claimed in independent claim 37 require that the phosphate group(s) are bonded to a group of formula $R_3N(R_6)(R_7)R^8$. Accordingly, Hong does not disclose each and every element of independent claim 10 or independent claim 37.

Since anticipation requires that each and every element of a claim must be taught by a single prior art reference, neither Surles, Meyer, or Hong anticipate independent claim 1, as amended.

CONCLUSION

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

Applicants also submit herewith is a Petition for Extension of Time with provision for the required fee to extend the time for responding by 1 month from September 3, 2004 to October 4 2004, since October 3, 2004 is a Sunday.

No fees are believed to be required for this submission. Should any fees be required, however, please charge those fees to Morgan, Lewis & Bockius LLP deposit account no. 50-0310.

Date September 29, 2004

Respectfully submitted,

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